NHS
National Institute for Health and Clinical Excellence

Understanding NICE guidance

Information for people who use NHS services

Closing the left atrial appendage of the heart by keyhole surgery to prevent stroke in people with non-valvular atrial fibrillation

NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This leaflet is about when and how treating non-valvular atrial fibrillation by keyhole surgery to close the left atrial appendage (LAA) of the heart to prevent stroke can be used in the NHS. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe atrial fibrillation or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on the back page.

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What has NICE said?

There is not much good evidence about how well this procedure works or how safe it is. If a doctor wants to use keyhole surgery to close the LAA of the heart alongside surgical ablation for atrial fibrillation, they should make sure that extra steps are taken to explain the uncertainty about how well it works, as well as the uncertainty surrounding potential risks of the procedure. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this leaflet and other written information as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure.

Currently there is not enough evidence to be certain about how well this procedure works or how safe it is when used alone. For these reasons, NICE has said that this procedure should only be carried out alone as part of a research study. The research should help to determine which patients should have this procedure, and look at the rhythm of the heart after the procedure and record any deaths and short- or long-term problems, stroke in particular.

A specialist healthcare team should decide which patients should be offered this procedure. The team should include a heart surgeon and other healthcare professionals who are experienced in the management of atrial fibrillation in patients who are at risk of stroke. Alternative treatments to reduce the risk of stroke should be considered and discussed with patients. The procedure should be carried out only by cardiac surgeons with experience in keyhole chest (thoracoscopic) surgery and specific training in this procedure.

Keyhole surgery to close the left atrial appendage of the heart

This procedure may not be the only possible treatment for atrial fibrillation. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

The medical name for this procedure is 'thoracoscopic exclusion of the left atrial appendage (LAA)'. The procedure is not described in detail here – please talk to your specialist for a full description.

Atrial fibrillation is the irregular and rapid beating of the upper two chambers of the heart (atria). People with atrial fibrillation have an increased risk of blood clots forming in the heart. These blood clots can form in the LAA (a small sac off the left atrium) and cause a stroke by travelling from the LAA and blocking a blood vessel in the brain.

Blood-thinning medicines are often given to reduce the risk of stroke. Surgery to insert a special device that blocks the LAA may be another treatment option.

This procedure is usually carried out with the patient under a general anaesthetic and often alongside radiofrequency or microwave ablation to treat atrial fibrillation, Small incisions are made in the chest wall, through which a camera and instruments are inserted. The right lung is usually deflated to allow access and the LAA is then closed, usually with staples. A chest drain may be used to remove fluid until the lung is re-expanded.

What does this mean for me?

If your doctor has offered you this procedure alongside surgical ablation for atrial fibrillation, he or she should tell you that NICE has decided that the benefits and risks are uncertain. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved in having the procedure and discuss the possible benefits and risks with you. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your doctor before making your decision.

Your doctor can only offer you this procedure alone as part of a research study. NICE has recommended that some details should be collected about every patient who has this procedure alone in the UK. Your doctor may ask you if details of your procedure can be used in this way. Your doctor will give you more information about this.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 6 studies on this procedure.

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

How well does the procedure work?

A study of 100 patients treated with radiofrequency ablation, of whom 85 were also treated with the LAA closure procedure, reported stroke in 2 patients and transient ischaemic attack (a type of mini-stroke) in 2 patients out of 88 patients who were monitored for 2 years.

A study of 15 patients treated by the procedure alone reported that 1 patient had a fatal stroke 55 months after the procedure.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that the aims of the procedure include complete closure and healing over of the LAA, and prevention of blood clots circulating in the blood, which could cause stroke and transient ischaemic attack.

Risks and possible problems

In the study of 100 patients, death was reported in 3 patients, and surgery involving an additional incision to control bleeding was required during the procedure in 3 patients.

Open surgery for bleeding from the LAA following the procedure was needed in 1 patient in the study of 15 patients. In the study of 30 patients, the type of procedure was changed to open surgery with the breastbone divided in 1 patient due to severe scar tissue in the space around the lungs (pleural adhsions), and 2 patients required drainage of air from the chest cavity after removal of chest drains.

One patient had long-lasting air leakage and another had sharp stabbing chest pain in the study of 15 patients. A patient from a study of 81 patients had a heart attack from which they recovered within 12 days.

As well as looking at these studies, NICE also asked expert advisers for their views. The advisers said that possible problems are incomplete closure of the LAA and nerve pain from the incision sites.

More information about atrial fibrillation

NHS Choices (**www.nhs.uk**) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support. For details of all NICE guidance on atrial fibrillation, visit our website at **www.nice.org.uk**

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see **www.nice.org.uk/aboutguidance**

This leaflet is about 'Thoracoscopic exclusion of the left atrial appendage (with or without surgical ablation) for non-valvular atrial fibrillation for the prevention of thromboembolism'. This leaflet and the full guidance aimed at healthcare professionals are available at **www.nice.org.uk/guidance/IPG400**

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2578). The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.

National Institute for Health and Clinical Excellence
MidCity Place, 71 High Holborn, London, WC1V 6NA; **www.nice.org.uk**

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